

Forty-Three Attorneys General Reach Consumer Protection Settlement With Bristol-Myers Squibb Company Over Abilify Marketing

Delaware Attorney General Matt Denn and 42 other Attorneys General have reached a settlement with Bristol-Myers Squibb Company ("BMS") related to the drug company's alleged improper marketing of Abilify, an atypical antipsychotic drug. An administrative complaint filed today along with a settlement agreement alleges that BMS engaged in deceptive trade practices when it marketed Abilify. The settlement restricts future claims about Abilify and limits financial incentives to sales representatives and health care providers.

Abilify is the brand name for the prescription drug aripiprazole. The drug was originally approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in 2002. Since then, the FDA has approved various formulations of Abilify for several indications. The complaint by the 43 AGs, however, alleges that BMS promoted Abilify for use in elderly patients with symptoms consistent with dementia and Alzheimer's disease despite the lack of FDA approval for these uses and without first establishing the drug's safety and efficacy for those uses. In 2006, Abilify received a "black box" warning stating that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death. Additionally, the complaint alleges that BMS promoted Abilify for uses in children not approved by the FDA. Moreover, the complaint alleges that BMS minimized and misrepresented risks thereby making false and misleading representations about

Abilify's risks. The complaint further alleges that BMS also overstated the findings of scientific studies by not revealing limitations that would materially affect the interpretation of the study results. The active ingredient in Abilify, aripiprazole, is now available as a generic, but several product formulations are still protected by patent.

As a result of Thursday's settlement, BMS' marketing of any formulation containing the active ingredient aripiprazole will be restricted. BMS will be prohibited from making false or misleading claims about Abilify, about its safety or efficacy in comparison with other drugs, and about the implications of clinical studies relating to the drug. BMS will also be subject to limitations on financial incentives to sales representatives and health care providers, dissemination of information that may promote off-label use of Abilify, and other practices affecting off-label promotion.

The settlement also stipulates that BMS pay a total of \$19.5 million to the states and District of Columbia. Delaware's Consumer Protection Fund will receive \$389,677, which pays for the Attorney General's work on consumer fraud and deceptive trade practice matters and other consumer-oriented investigations and legal actions.

The Attorneys General from Maryland and Kentucky led the Executive Committee states' negotiation of the settlement of Bristol-Myers Squibb Company's marketing and promotional practices. The Executive Committee states include Arizona, Colorado, Delaware, District of Columbia, Florida, Kentucky, Maryland, North Carolina, Ohio, and Pennsylvania. The participating states in the settlement are: Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania,

Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

Deputy Attorney General Stephen McDonald of DOJ's Consumer Protection Unit, represented Delaware in the settlement.